***Draft* Meeting Summary**
Certificate of Need (CON) Modernization Task Force
Maryland Health Care Commission
Meeting of Friday, November 9, 2018
MHCC Offices, 4160 Patterson Avenue, Baltimore, MD

Committee Members in Attendance
Randolph Sergent, Chair
Ellen Cooper (via phone)
Elizabeth Hafey
Ann Horton
Andrea Hyatt (via phone)
Ben Lowentritt
Brett McCone
Lou Grimmel
Mark Meade
Michael O'Grady (via phone)
Richard Przywara
Barry Rosen
Andrew Solberg
Renee Webster

MHCC Staff in Attendance
Ben Steffen
Linda Cole
Kevin McDonald
Sarah Pendley

MHCC Consultants in Attendance
Patrick Redman (via phone)
Samantha Sender
Thomas Werthman

Others in Attendance
Jack Eller
Danna Kauffman
Marta Harding (via phone)
Anne Langley
Paul Miller
Tyler Pickrel
Daniel Shattuck

Agenda Item 1: Call to Order, Welcome and Introductions

Chairman Randolph Sergent opened the meeting by identifying Task Force members, MHCC staff, and additional people in attendance. Attendees on the phone identified themselves.

Agenda Item 2: Approval of October 12, 2018 Task Force Meeting Summary

Chairman Sergent asked if there were any comments on the meeting summary of October 12, 2018. No comments were received.

Agenda Item 3: Staff Resources and the Organizational Foundation for Reform

Ben Steffen provided a roadmap of where the Task Force currently stands, and recommended that the Task Force members focus their discussion on the recommendations. These recommendations are identified based on their categorization:

- regulatory reforms to begin immediately,
    - MHCC has staffing and resource constraints that may impact immediacy;
    - Commissioner Sergent also noted process for regulatory reform can be slow.
- short-term statutory changes, and
- study recommendations that cover broader reforms, and include convening work groups for additional study:
    - removing certain services from the scope of CON, but retaining gatekeeper functions to protect against 'bad actors'; and,,
    - modernizing other CON actions that would require coordination with the HSCRC.

Mr. Steffen also reviewed capacity within MHCC staff and noted that the small staff at MHCC are not immediately interchangeable when one division is busier than another. He also reviewed workload of Planning and Development staff, particularly around revision of State Health Plans (SHP), increased backlog of project applications, and the fact that the number of interested parties has grown. Exemptions requests have also grown. Focusing on streamlining the procedural processes may be a place to start.

Mr. Steffen addressed specific staff teams that would work on the proposed reforms, and the significant challenges that will need to be met, given the work required.

Brett McCone asked about prioritization of SHP chapter reviews, given MHCC resource limitations. Mr. Steffen discussed current methods for SHP review and revision.

Agenda Item 4: Review of Recommendations

Chairman Sergent encouraged Task Force members to provide input, but reminded the Task Force that the Commissioners' could modify recommendations prior to submission to the Committees. Mr. Kevin McDonald and Ms. Linda Cole presented the series of recommendations for reform that will be included in the report.

Addressing the recommendation section contained in the draft report, Mr. McDonald noted three buckets of recommendations:

- Regulatory reforms that can be started immediately
- Statutory reforms that can be addressed in the new two legislative sessions
- Statutory and regulatory changes that will require more time.

Regarding ***regulatory reforms that can be started immediately***, Mr. McDonald listed the reforms as proposed in the "recommendations" section of the draft report:

1. **Identify the State Health Plan chapters that are most in need of updating and which offer the greatest potential to meet reform objectives and prioritize their revision. Simultaneously review and revise the procedural regulations governing CON application review.**

   1a. In updating SHP chapters, limit SHP standards to consideration of project need, viability, impact, applicant qualifications. (Mr. McDonald added impact to this list)

- **Address quality of care and "gatekeeper" functions by setting performance or track record qualification standards that must be met to become an applicant;**

- **Standards that do not address these five specific criteria should only be included if absolutely necessary to the particular characteristics of a health care facility or the standard can be linked to solving a specific problem;**

- **Eliminate extraneous standards or redefine standards that currently have low impact (e.g. charity care requirements for home health or hospice)**

There was discussion that applicant qualification standards will allow for the establishment of performance or track record thresholds that must be met in order to become an applicant and, as such, will become the single way in which CON regulation addresses quality of care, as a "gatekeeper. It was recommended that conditions of previous CONs should also be considered.

1b. Create an abbreviated review process for all uncontested projects that do not involve:

a) establishment of a health care facility;

b) relocation of a health care facility;

c) the introduction by a hospital of cardiac surgery or organ transplantation.
An abbreviated review process will include:

- **A *goal* --not a hard and fast requirement --to limit completeness review to one round of questions and responses before docketing an application as complete. (*This goal presupposes reforms to significantly reduce and better define SHP standards*.)**
- **Issuance of a staff recommendation within 60 days of docketing and final action by the Commission within 90 days of docketing.**

Regarding the abbreviated review process discussed in 1.b., Mr. McDonald noted this would lead to a greater number of disapproval recommendations if there is no opportunity to revise – "be careful what you wish for." Mr. McCone asked if the abbreviated process would consider changes in service capacity. Mr. McDonald responded yes. Mr. McCone applauded the effort, but voiced concern about creating another process, rather than cleaning up of present process might be better. Mr. McDonald agreed that the cleaning up of existing process could be better than the creation of a new process. Mr. Solberg thought that renovation of facilities; and establishment of a new service in an existing health care facility would fit under the abbreviated process. He asked if the establishment of NICUs and burn units would require a CON. Mr. Steffen stated that these changes would require a statutory changes. Mr. Sergent cautioned against recommendations that would require statutory changes, as such changes take far longer to implement. Mr. Steffen also pointed out that starting immediately doesn't necessarily mean completed quickly because the MHCC's process for changing a SHP requires don't happen quickly. Dr. Ben Lowentritt asked about exemption process versus expedited review process, and asked whether distinction could made clear in draft and implemented, where possible, through a change in regulations.

1c. Revise performance requirements for approved projects to include a deadline for obligating the capital expenditure and initiating construction, but eliminating project completion deadlines.

- **Timely obligation and initiation of construction will result in a 12-month extension with subsequent requirements to report progress (in essence, an annual progress report) and obtain additional 12-month extensions until project completion.**
- **Failure to timely obligate and initiate construction will void the CON. Projects that do not involve construction will continue to have a deadline for completing the project.**

Regarding the recommendations in 1. c., Mr. Richard Przywara questioned the timely obligation requirements, when external construction reviews or permit requests can adversely impact these deadlines. Mr. McDonald noted that extensions can be requested under the regulations, particularly under these circumstances. Mr. Solberg noted that historically the Commission has been responsive to giving extensions under these circumstances.

1d. Make the review of changes in approved projects staff review function with approval by the Executive Director. Limit required change reviews to:

- **changes in the financing plan that require additional debt financing and/or extraordinary adjustment of a hospital's budgeted revenue and**
- **changes in "medical services" approved to be provided by the facility.**

Continue current list of impermissible changes.

Mr. Solberg supported this recommendation, except in cases of contested cases or in circumstances in which applications would be denied. Mr. McCone also agreed to this proposal, except in cases of change of location.

2. Create a waiver of CON requirements for:

- **a hospital capital project that is endorsed by the HSCRC staff as a viable approach for reducing the total cost of care consistent with HSCRC's TCoC model; and**

- **allow docketing of an alternative models for post-acute care that is endorsed by the HSCRC staff as a viable approach for reducing the total cost of care consistent with Maryland's TCoC model**

Mr. McCone noted the impetus behind this recommendation is to transform service delivery. He observed that that there needs to be a consideration from a capital funding standpoint, as hospitals funding for hospitals occurs in rates. Mr. Sergent noted the wrinkles in regulations that need to be addressed, but the broad mandate for coordination between providers is accomplished in this recommendation. Ann Horton asked what was meant by "alternative models for post-acute care." Ms. Cole responded with the example of nursing homes working with hospitals to provide post-acute care, and the exception to the docketing rule if the hospital and nursing home can develop a project approved by HSCRC that improves TCoC. This recommendation is part of broader model to expand TCoC beyond hospitals. Dr. Lowentritt believed that recommendation should specify for all other health facilities.

In the context of allowing service expansion absent defined need, Mr. Lou Grimmel asked about how need doesn't come into consideration when allowing service expansion for existing providers, and how this will negatively affect TCoC. He also asked why this proposal doesn't require a statutory change. Mr. Steffen noted this is a docketing exception, and this provides an incentive for hospitals to collaborate. Mr. Grimmel was emphatic that hospitals have to want to collaborate and are currently disinclined to work with existing providers.

Mr. McDonald noted the lack of language clarity in the recommendation. He agreed that the language should read "and allow for docketing of projects that incorporate innovative alternative payment models…." This change would allow MHCC to consider certain capital projects for the docketing if those projects included innovative alternative models. Ms. Ellen Cooper brought up a question about charity care (from paragraph 1.a.i): is charity care a requirement for all entities, or just home health care? Mr. McDonald responded that charity care is in almost all of the SHP chapters. Charity care in home health was directed specifically to streamlining home health agency CON review, since the average charity care in home health is 1%, or less. Despite being so low, it takes up a disproportionate share of the review and was provided as an example of a low-impact standard to remove. Barry Rosen noted the 5 recommended changes to the SHPs from the power point are considerably broader than the revisions to charity care policy that had been discussed in the Task Force. He argued that the staff has to decide how broadly if want to undertake reform. Mr. Steffen discussed the reason for the charity care example as provided in the recommendation. Ms. Ann Horton said that the concept that a charity care standard is a burden must be a staff recommendation, since it did not come from the home health industry.

Mr. Przywara asked how the staff reached conclusion about levels of charity care and basis for selecting a level of charity care that an applicant must meet. Ms. Cole responded that the level of charity care is derived from provider surveys collected by the MHCC. Mr. Solberg added that minimum threshold is often a derivative of average or median level of charity provided in a jurisdiction or a region. Mr. McDonald concluded by adding that a charity care benchmark is derived empirically based on what other similar operators are providing in the jurisdiction or the region. Mr. Przywara asked, as an example, if a group of hospices or home health agencies are providing less than 1%, will a new applicant be held to the sane standard? Mr. McDonald responded in the affirmative. Mr. Rosen argued that if reporting charity care serves no purpose, it should fall away, or if it serves a purpose, a decision should be made as to what the goal is, and then the process should meet the goal. Ms. Cole responded that for current CON reviews

of home health agencies, this is a required standard. In terms of discussion for future plan chapter revisions, it can be revised.

Mr. McCone noted his belief that the intent of these standards is, by linking such requirements to other CON processes, it is an example of one of the only times providers can be required to have some process to provide free and indigent care. Ms. Andrea Hyatt noted that some providers have no control over charity cases. She argued that Ambulatory Surgery Centers (ASCs) are reliant on physicians to bring in such cases. Mr. Solberg offered a few points: 1) charity care policies are responses to efforts to ensure access, and 2) every standard should be based on resolving a known problem.

In terms of charity care polices, each chapter of the SHP should identify what is the financial access faced by certain patients for that type of service: if there is a problem, then there should be a standard. If there is no identified problem, but merely a desire, then the policy is ineffective and applicants struggle to meet a policy that has no impact. Mr. Solberg disagreed with the contention that ASCs were passive in the level of charity care that was delivered. In his experience with his clients, and their processes with owners (physicians) could control the level of charity care in their facilities, insured patients were treated at the ASC and uninsured and Medicaid patients were treated at the hospital OPD. Ms. Hyatt countered that elective cases can't be taken to a hospital and performed as charity care. There was some discussion of what happens to charity care if the TCoC model unravels. Mr. Steffen responded, that if model goes away in Maryland, many processes (including charity care) would have to be rethought. Mr. McDonald clarified, again, that the recommendation allows for docketing of alternative models, as opposed to waiving CON requirements.

Ms. Cole reviewed recommendations for ***statutory reforms that can be addressed in the upcoming legislative sessions.***

Statutory Changes to Be Sought in the 2019 or 2020 Legislative Session

1. **Eliminate capital expenditures by a health care facility as an action requiring or permitting CON approval, leaving all definitions of projects requiring CON approval as categorical with respect to the changes in a health care facility, no matter what capital expenditure is required.**

Mr. McCone noted there could be an increased demand for services, depending on whether projects get approved and volume as a result gets generated. This refers to projects other than hospitals. Mr. McCone also recommended aligning the CON statute with the Alternative Payment Models being developed by HSCRC.

2. **Replace existing capital expenditure threshold with a requirement that hospital obtain CON approval for a project with an estimated expenditure that exceeds a specified proportion of the hospital's annual budgeted revenue and for which it is requesting an extraordinary adjustment in budgeted revenue, based on an increase in capital costs.**

Mr. Solberg stated that this recommendation should only be made in collaboration with the HSCRC. Mr. McCone believed that some review process needs to remain. Mr. Grimmel asked if HSCRC should approve rate request before the CON is approved. Mr. Solberg noted complexity of negotiations between

MHCC, HSCRC and applicant. He argues that HSCRC should not be the exclusive gatekeeper for projects. Mr. McCone noted the need to revise the HSCRC capital policy as a first step in this process.

3. **Change the CON statute to include only these criteria: a) alignment with the State Health Plan standards; b) Need c) Viability of the project and the facility; d) Impact on cost and charges. This would remove the criteria pertaining to Cost Effectiveness and identification of alternatives, and Compliance with the terms and conditions of previous CONs the applicant has received.**

Mr. Solberg had concern with MHCC serving as a gatekeeper, and not holding applicants to account with conditions of previous CONs. Mr. Rosen noted that alignment with recommendation 1a above and that the recommendations need to be consistent. Dr. Lowentritt didn't want to limit MHCC in dealing with bad actors. Ms. Cole noted that compliance with the conditions and requirements established in previous CONs is evaluated by staff during the review of a CON application. If an applicant failed to meet the conditions of a previous CON, at a minimum that applicant will be asked to explain.

4. **Eliminate from CON review changes in bed capacity by an alcoholism and drug abuse treatment intermediate care facility that has level 3.7 beds or by a residential treatment center.**

Staff confirmed that this applies to existing providers. Mr. Rosen noted that this recommendation could violate the Interstate Commerce Clause. Mr. Przywara argued that this recommendation only referred to those providers who have been properly vetted, not to prevent entrance of entities from outside the state.

5. **Eliminate requirement of CON review changes in acute psychiatric bed capacity by a hospital.**

Mr. McCone believed that psychiatric SHP chapter needs to be revised given the age of the chapter. In response to a question from the Task Force, staff confirmed that psychiatric specialty hospitals are not included under this exemption.

6. **Eliminate requirement of CON review changes in hospice inpatient bed capacity or the establishment of bed capacity by a general hospice.**

Currently, existing licensed general hospices cannot develop a general inpatient hospice facility without a CON. This change would provide greater flexibility for an existing general hospice to establish an inpatient hospice or to expand one already in operation. The change would only apply to general hospices already operating in the State.

7. **Define ambulatory surgical facility (ASF) as an outpatient surgical center with three or more operating rooms instead of the current definition's threshold of two operating rooms.**

Mr. Steffen reviewed the current approach to CON oversight. He stated that in 2017 the Commission had created an exemption process for physician-owned enterprises to establish up to a two operating room ASFs. Previously, physician-owned operations could establish a one operating room facility, known as a physician-owned surgical facility (POSC), through a determination by the MHCC staff that the facility

was not subject to CON review. Somewhat different processes for facilities of similar capacity is unnecessarily complex. Moreover, these processes apply only to physician-owned facilities. Investor-owned and various joint partnerships are required to obtain a CON regardless of capacity. The recommendation would allow ASFs (non-rate regulated facilities) of two operating rooms or less to operate without CON approval while maintaining CON regulation for ASFs of three operating rooms or more. The recommendation would allow all also persons, including hospitals, to establish outpatient surgical facilities without CON approval (non-rate regulated facilities) with one or two operating rooms. Mr. Solberg suggested that HSCRC also be consulted on this recommendation.

8. **Limit the requirement for CON approval of changes in operating room capacity by hospitals to the rate-regulated hospital setting, i.e., a general hospital and any other entity would have the ability, under the new definition of ambulatory surgical facility, to establish one or two-operating room outpatient surgical centers without CON approval, but with a determination of coverage after a plan review by staff**

Dr. Lowentritt noted that if this new recommendation is adopted, hospitals will no longer be required to reduce operating rooms in a corresponding fashion. Moving operating rooms from a regulated to an unregulated space will allow hospitals to establish new capacity without TCoC considerations. He continued that without CON, HSCRC might not be sensitive enough to respond to these actions. Mr. Solberg noted that if cases are moved to a lower-cost entity, there needs to be a TCoC recognition. Mr. Steffen observed that Dr. Lowentritt's concern would be remedied by HSCRC triggering a Global Budget Revenue (GBR) reduction for that hospital. Commissioner Sergent noted that HSCRC will have to develop methods to root out hospitals who could open shell corporations to open ASCs.

9. **Establish deemed approval for uncontested project reviews eligible for an abbreviated project review process if final action by the Commission does not occur within 90 days**

Mr. McCone asked if this "abbreviated project review" is an additional process. He stated that if there are no new services and no interested parties, then the MHCC could simplify the existing process.

Ms. Cole addressed the final series of recommendations,

Areas for Further Study from which Further Regulatory and Statutory Changes Are Likely to Emerge:

1. **Engage with stakeholders such as the Home Health, Hospice, Alcohol and Drug treatment, Residential Treatment Center sectors and the Maryland Department of Health to consider developing alternatives to CON regulation for accomplishing the "gatekeeper" function of:**

    - **keeping out organizations with poor track records in quality of care and/or integrity, and;**

    - **expanding the number of such facilities gradually.**

The objectives would be to:

- **Eliminate CON regulation for these health care facility categories with MDH incorporating the gatekeeper function into the facility licensure process; or**
- **Establish MHCC's role in regulating these facility categories solely as a gatekeeper:**
    - **Any facility of this type that gets a clean bill of health in a background check and character and competence review would be issued a CON, without further review….as long as that is compatible with the gradual expansion of new providers.**
    - **Establish specific deadlines for recommendations.**

Mr. Mark Meade noted the need for some type of protection against bad actors who change their business entity name before entering the state. There needs to be a review of entity ownership to prevent this from occurring. Mr. Przywara was concerned CON would be eliminated before new process is developed. Mr. Steffen noted that the recommendation requires study and collaboration among agencies that would be required to implement a 'gatekeeper' function.

2. **Engage with HSCRC to examine how hospital CON project review and the total cost of care project can be further integrated. The objective would be to limit hospital projects requiring CON review and to improve MHCC's use of HSCRC expertise in consideration of project feasibility and project and facility viability.**

Mr. McCone noted the need for the HSCRC to modernize the capital policy is a first step before any recommendations are developed out of a study. Dr. Lowentritt believed the HSCRC would still serve as a gatekeeper to other quality and value initiatives as new projects are developed, the "CMMI for Maryland."

3. **Consider structural changes in how the Commission handles CON project reviews in light of creating an abbreviated process for most reviews and providing meaningful participation by the public in the regulatory process. Possible changes could include use of a project review committee. The objective would be further streamlining the review process and facilitating more public engagement.**

Mr. McCone asked about abbreviated process for most reviews, how are differences defined. He asked for clarification of the "project review committee". Mr. Steffen defined the project review committee as a subset of Commissioners that would address certain types of projects. These projects would be uncontested and routine. Mr. Steffen noted that an appeal process could be needed to enable the full Commission to review the project review committee's decision.

Agenda Item 5: Plans for a December 3, 2018 Meeting

Mr. Steffen offered this meeting could be conducted by phone. Mr. McCone asked it to be offered in person. Mr. Steffen agreed that meeting would be held in person at MHCC offices, starting at 9:30 am.

Agenda Item 6: Public Comment

Mr. Steffen stated that the MHCC would consider final report at the December 20, 2018 Commission meeting. MHCC would discuss with the Administration on whether statutory changes would be offered by this year. Mr. Sergent asked for simple comments, given tight time frame, and requested that they be submitted at least a week before the final meeting to ensure Commissioners had sufficient time for review.

Chairman Sergent thanked everyone and ended the meeting.